

REMARKS

The pending Office Action addresses and rejects claims 1, 2, 7-10, 13-20, 42, 43, and 46-50.

Claim Amendments

Claims 1, 42, 43, and 46 are amended to recite a spinal fixation system that includes a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members. The remaining claims are amended to recite a spinal fixation system. Support for this amendment can be found in the specification, for example, in paragraph 29. No new matter is added.

Drawings

The Examiner objects to the drawings because they are informal and illegible due to poor print quality. New drawings are submitted herewith to overcome this objection.

Rejections Pursuant to 35 U.S.C. §102

The Examiner continues to reject claims 1, 2, 7, 9, 13-16, 20, 42, and 43 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,536 of Yue.

Independent claims 1, 42, and 43 are amended as noted above to include a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members. Yue does not teach or suggest a system that includes a spinal anchor implantable in bone. Yue is directed to an orthopedic plate for use in correcting problems with the long bones of the body, such as the shoulder, knee, ankle, and hip. Yue does not contemplate implantation in the spine, let alone using the device with a spinal anchor.

In addition, the Examiner continues to overlook the claim language. Specifically, claim 1 requires a fastening element that is adapted to mate to the male connector to cause the male connector to engage the mating element and lock the elongate members in a fixed position relative to one another. Claims 42 and 43 require a fastening element that causes one of the elongate members to engage a

mating element to lock the elongate members in a fixed position relative to one another. Yue lacks a fastening element, a mating element, and a male connector in the configuration required by the claimed invention. The only component of Yue that could be considered a mating element is the pivot pin connecting the blade portion and the side plate, as discussed in the previous response. In the pending Office Action, the Examiner argues that “the mating element is engaged such that the elongate members are locked in a fixed position, e.g., as about their pivot axis and in all but one plane, relative to one another.” The mating element, e.g., the pin of Yue, is not engaged by the male connector, e.g., the blade portion or the side plate, to lock the blade portion and the side plate relative to one another. Rather, the pin is freely rotatably disposed through the blade portion and the side plate and cannot be used in a manner that locks the blade portion and the side plate relative to one another.

Yue also does not teach or suggest any components that would function as the fastening element recited in the claim to mate to either the blade portion or the side plate to cause it to engage the mating element, e.g., the pivot pin. Yue also does not teach or suggest that either the blade portion or the side plate engages the pivot pin to lock the blade portion and side plate in a fixed position, as required the claims.

Accordingly, claims 1, 42, and 43, as well as claims 2, 7-9, 13-16, and 20 which depend therefrom, distinguish over Yue and represent allowable subject matter.

Claim Rejections under 35 U.S.C. §103

(1) U.S. Patent No. 5,509,328 of Lai

Claims 1, 2, 13-20, 42, 43, 46, 48, and 49 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,509,328 of Lai. The Examiner argues that Lai discloses the claimed invention, except that Lai does not specify the material of the device. The Examiner states that “[i]t would have been obvious to have formed the device from, e.g., titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability of the

intended use a matter of obvious design choice" (Office Action, page 4). Applicants respectfully disagree.

At the outset, Lai does not teach or suggest a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members. Lai is directed to a bicycle handlebar design, and does not ever mention spinal anchors or anything else implantable in bone.

Moreover, for reasons already addressed by Applicants, Lai's bicycle handlebar is not an implantable spinal fixation rod, and it is hard to imagine any successful use of a bicycle handlebar in spinal fixation surgery. Regardless of whether the Examiner can properly rely on Lai to disclose an implantable spinal fixation rod, Lai cannot be relied on to formulate an obviousness rejection over the pending claims because the cited reference represents non-analogous art. In order to rely on a reference in analyzing the obviousness of the subject matter at issue, the reference must be analogous prior art. A reference is "analogous" if (1) the reference is within the field of the inventor's endeavor, and if it is not then (2) the reference must be reasonably pertinent to the particular problem with which the inventor was involved.

Lai is not within the field of the inventor's endeavor. Lai is directed to a bicycle handlebar. The present invention, on the other hand, is directed toward implantable devices and methods for spinal fixation. No person having ordinary skill in the art would rely on a reference directed toward *a bicycle handlebar* to modify a device for *spinal fixation*. These are distinct devices that are used for very different purposes.

Lai is also not reasonably pertinent to the problem to be solved, namely spinal fixation. Applicants refer the Examiner to MPEP 2141.01(a) and *In re Clay*, 966 F.2d 656, 659 ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.") The subject matter of Lai would not have logically been brought the attention of the inventor of the claimed subject matter as no inventor working in the area of spinal fixation would logically look to bicycle parts to solve the pertinent problem. Futher,

MPEP 2141.01(a)(IV) includes examples of analogy in the mechanical arts. For example, in *In re Oetiker*, 977 F.2d 1443,

Applicant claimed an improvement in a hose clamp which differed from the prior art in the presence of a preassembly "hook" which maintained the preassembly condition of the clamp and disengaged automatically when the clamp was tightened. The Board relied upon a reference which disclosed a hook and eye fastener for use in garments, reasoning that all hooking problems are analogous. The court held the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments.

Like the above-referenced case, while the Examiner may argue that Lai is analogous because it addressed an adjustable connection, an inventor seeking to solve a problem regarding spinal fixation would not be reasonably expected or motivated to look to a bicycle part in solving that problem. Accordingly, the bicycle handlebars of Lai are not within the field of inventors' endeavor, namely spinal fixation. Lai is therefore non-analogous art that cannot be relied on to formulate an obviousness rejection. Thus, claims 1, 42, 43, and 46, as well as claims 2, 13-20, 48, and 49 which depend therefrom, distinguish over Lai and represent allowable subject matter.

(2) U.S. Patent No. 6,007,536 of Yue

Claims 8, 10, 47, and 50 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,007,536 of Yue.

As discussed above, independent claim 1 distinguishes over Yue. Thus, claims 8 and 10 are allowable at least because they depend from allowable claim 1.

Claims 47 and 50 depend from claim 46, which likewise distinguishes over Yue. Similar to claims 1, 42, and 43, claims 46 likewise requires a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members. As discussed above, this feature is not

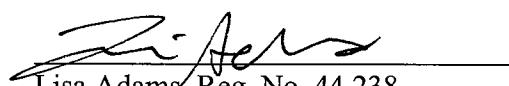
taught or suggested by Yue. In addition, claim 46 requires a clamping mechanism formed on a terminal end of a first elongate element. The Examiner argues that “the device of Yue comprises a clamping mechanism at its terminal end at least because the device is rigid and is capable of receiving an object to be clamped between the terminal ends thereof.” Applicant respectfully disagree with the Examiner’s characterization of Yue. The blade portion (1) and the side plate (2) of Yue do not include any features on their terminal ends, clamping mechanism or otherwise. The fact that the blade portion and side plate are rigid components is irrelevant as to whether either of these components *includes* a clamping mechanism formed thereon. Accordingly, independent claim 46 distinguishes over Yue. Claims 47 and 50 are therefore allowable at least because they depend from allowable claim 46.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application..

Respectfully submitted,

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